

S/N 09/933,938

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Pathiraja A. Gunatillake et al.

Examiner: Rabon Sergent

Serial No.: 09/933,938

Group Art Unit: 1711

Filed: August 21, 2001

Docket: 1207.008US1

Title: SILOXANE-CONTAINING POLYURETHANE-UREA COMPOSITIONS

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, **PATHIRAJA ARACHICHILLAGE GUNATILLAKE**, declare and say as follows:

1. I am a co-inventor of the subject matter claimed in the above-identified U.S. patent application, U.S. application Serial No. 09/933,938, filed on August 21, 1997.
2. I have read and am familiar with the Office Action dated June 7, 2005 with respect to the above-identified application, and make this Declaration in support of the patentability of the claims of U.S. application Serial No. 09/933,938.
3. In the Office Action mailed June 7, 2005, the Examiner rejected claims 63-79, 81-108, 111-112 and 117-121 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Szycher et al. ('627) or WO 98/13405 or JP 4-248826, each in view of Li et al. ('724) and Ohtaki et al. ('805).

The following experiments were carried out by scientists at AorTech Biomaterials Pty Ltd to my satisfaction in order to compare claimed compositions of the invention with representative compositions of the references.

4. **Comparison with WO 98/13405**

| Formulation | Fail strain % | UTS (MPa) | Modulus (MPa) | Tear Strength (N/mm) |
|---|---------------|-----------|---------------|----------------------|
| Composition 1 in Example 1 of present application | 370 | 26.6 | 100 | 68 |

| | | | | |
|--|-----|----|----|----|
| with mixed amine/hydroxyl chain extender | | | | |
| Composition of WO 98/13405 same as Composition 1 of present application but with no amine chain extender | 300 | 25 | 55 | 60 |

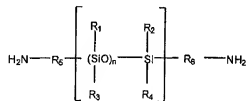
As is clear from the above Table, a mixed amine chain extender system has a significant impact on the mechanical properties, especially the modulus, that is almost doubled. This demonstrates a substantial difference in mechanical properties between the compounds of present claim 104 and WO 98/13405.

5. **Comparison with Li et al. (US 5,221,724)**

Polyurethane urea polymers (ATPS-50) were synthesized according to the formulation suggested in Li et al (US 5,221,724). The polymers were compared with Composition 1 in Example 1 of the present application. The example ATPS-50 in Table 1, Col 6 of the Li et al. patent was chosen as the polymer to synthesize as being the only example that clearly focused on the formulation approach (described below).

As is apparent from the results section (below), the approach in the Li et al. patent lead to a mechanically inferior polymer as compared to the polymers of the present application. The prior art polymers were also restricted in their ability to phase mix as is evidenced by the lower molecular weights produced.

The Li et al. patent discloses the reaction of compounds of the following formula:



(1)

i.e., Aminopropyl-polydimethylsiloxane (ATPS) (Li et al. n = 1-200) is recited with diphenylmethane diisocyanate (MDI) to form a polyurethane urea based soft segment. Further reaction with different chain extenders, such as butanediol (BDO), ethylene diamine (ED) and N-methyldiethanolamine (MDEA) is carried out to form the hard segment of the polymer. The aim of Li et al. is to use polyurea based soft segments in order to increase the compatibility of the polar MDI with the non-polar Si chains. The approach of the present application is to retain polyurethane linkages in the polymer and use polar end groups attached to the PDMS molecule to obtain phase compatibility. The use of the ether based polyol in PHMO also achieves a similar purpose of compatibilisation. Our approach precludes urea formation in the soft segment. All the urea formation occurs in the hard segment.

Results

Sample ATPS-50 in Table 1, Col 6 of the Li et al. patent was synthesized at three different molecular weights. The properties were compared with the examples from the present application (composition 1 and composition 2 from Example 1).

| Material | Sample | UTS (MPa) | % Elongation at break | Mn |
|---|---------------|-----------|-----------------------|--------|
| Patent example -Li et al | ATPS-50 | 16.8 | 4% | 28,000 |
| Reproduction of ATPS-50 in AorTech labs | 1 | 16.6 | 4% | 32,000 |
| | 2 | 17.7 | 3.2% | 41,500 |
| | 3 | 13.2 | 5.6% | 23,350 |
| Present Application | Composition 1 | 26.7 | 15.2% | 56,400 |
| | Composition 2 | 25.8 | 9.3% | 63,200 |

As the results show, the mechanical properties of the polymers obtained through the approach of the present application show higher ultimate tensile strength, higher elongation to

break and better molecular chain growth.

9. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

Dated: July 5, 2006

By: 

PATHIRAJA ARACHICHILLAGE GUNATILLAKE